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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,398	02/28/2002	Bruce A. Yankner	CMCC 654 DIV (2)	3779
23579	7590	02/24/2004	EXAMINER CRIARES, THEODORE J	
PATREA L. PABST HOLLAND & KNIGHT LLP SUITE 2000, ONE ATLANTIC CENTER 1201 WEST PEACHTREE STREET, N.E. ATLANTA, GA 30309-3400			ART UNIT 1617	
PAPER NUMBER				

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/086,398

Applicant(s)

YANKNER ET AL.

Examiner

Theodore J. Criares

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## CLAIMS 23-29 ARE PRESENTED FOR EXAMINATION

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the amount of compound which yields the claimed effect) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants' claims are, as admitted by applicants, drawn to a composition of matter. The applicants' arguments directed to the rejections under 102(a) and 103(a) are drawn to a method of using the claimed known composition not to how the art differs with respect to the claimed composition per se. Therefore, the rejection of June 6, 2003 are deemed proper and repeated herein as follows:

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 23-29 are rejected under 35 U.S.C. 102(a) as being anticipated by Hoffman et al., Wannamaker et al. and Speilvogel et al.

Applicants' claims, as stated above, are drawn to composition. Therefore, each of the references teach a composition of one of the applicants' claimed compositions or a compound used in a biological pathway as claimed by applicants' claims 23, 24, 27 and 28.

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Hoffman et al. Teach at column 1, lines 5-65, column, 2 line 50 to column 8, line 39 and column 9, lines 50-62 lovastatin, pravastatin and simvastatin of claim 24 and that each of these compounds inhibit cholesterol by inhibiting (claims 26 and 27) the enzyme, HMG CoA reductase as claimed in claim 24 and inherently decreasing the production of A $\beta$  to decrease blood levels as recited in claim 23. It is to be understood that these claimed known compounds as claimed by applicants are well known anti-cholesterol agents.

Wannamaker et al. disclose and teach at column 2, lines 12-17 and column 2, line 20 to column 3, line 16 that the compounds taught therein have activity of inhibiting 2,3-oxidosqualene cyclase to inhibit cholesterol as claimed in applicants' claims 27a and 28. The pharmaceutical compositions of the claimed biological pathway are taught at column 14, line 66 to column 14, line 44.

Spielvogel et al teach at column 8, lines 33-42 (see lines 38-42) a composition of claim 29 comprising nicotinic acid in a pharmaceutical formulation.

That applicants may have determined a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated and the effect are the same. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by claims 23, 24, 27 and 28

As stated in *In re Spada*, 911 F 2d 705; 15 USPQ2d 1655 (Fed. CR. 1990)  
"discovery of a new property or use of a previously known composition, even when that

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property and use are unobvious from the prior art, can not impart patentability to claims to the known composition." This is the basis for the rejection of claims 23, 26 and 27.

Claims 29 is rejected since it reads on claim 23 which is brawn to a composition "comprising".

The rejection under 35 U.S.C 102(a) is deemed proper.

***Claim Rejections - 35 USC § 103***

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wannamaker et al.

As stated above Wannamaker et al. teach the pharmaceutical formulation of compounds which inhibit 2,3-oxidosqualene cylase to inhibit cholesterol as claimed by applicants' claim 26 –28. the difference between the reference and applicants' claim 26 is that the reference fails to teach the uptake of dietary cholesterol. However, one skilled in the art would be motivated to use the compounds claimed in Wannamaker et al. to cause the uptake of dietary cholesterol since the reference teaches at column 16, lines 44-64 that the compounds can be within an oral form with an edible carrier.

The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 18 USPQ 2d 1885, (Fed. Cir. 1991). In view of the above rejection it is deemed that the evidence presented has established a prima facie case of obviousness. is presented.

None of the claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is (571) 272-0625. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Theodore J. Criares  
Primary Examiner  
Art Unit 1617

TJC  
2/21/04